PhaseBio Reports Third-Quarter 2021 Financial Results and Recent Business Highlights

November 10, 2021

Announced topline data from Phase 2b clinical trial of bentracimab, which was conducted in healthy, older volunteers 50-80 years old

Reached interim enrollment milestone for the REVERSE-IT Phase 3 trial of bentracimab

Prespecified interim analysis of pivotal REVERSE-IT Phase 3 trial to be presented during late-breaking science session on November 15 at the American Heart Association's Scientific Sessions 2021

PhaseBio to host analyst and investor event on November 15 at 12:30 pm ET to review interim analysis of the REVERSE-IT trial

MALVERN, Pa. & SAN DIEGO--(BUSINESS WIRE)--Nov. 10, 2021-- PhaseBio Pharmaceuticals, Inc. (Nasdaq: PHAS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases, today provided an update on corporate activities and reported third-quarter 2021 financial results.

"During the third quarter of 2021, we made important progress advancing our lead product candidate bentracimab closer to potential commercialization for patients in critical need of an antiplatelet reversal agent," said Jonathan P. Mow, Chief Executive Officer, PhaseBio Pharmaceuticals. "In August, we were pleased to achieve our interim enrollment milestone for the pivotal REVERSE-IT Phase 3 trial, and we look forward to presenting data from the prespecified interim analysis at the American Heart Association's Scientific Sessions on November 15. Looking ahead, we remain focused on targeting a Biologics License Application (BLA) submission in mid-2022 and are excited about the future prospects of potentially commercializing the first ticagrelor reversal agent for patients who need urgent surgery or suffer from spontaneous bleeding events."

Program Highlights and Corporate Updates

- **Prespecified Interim Analysis from Pivotal REVERSE-IT Phase 3 Trial to be Presented at the American Heart Association's Scientific Sessions 2021:** On November 15, 2021, at a late-breaking science session at the American Heart Association's Scientific Sessions 2021, PhaseBio will present a prespecified interim analysis from REVERSE-IT, the pivotal Phase 3 trial designed to study reversal of the antiplatelet effects of ticagrelor with bentracimab in patients who present with uncontrolled major or life-threatening bleeding or who require surgery or invasive procedure. Details about the upcoming presentation were set forth in PhaseBio's press release on October 6, 2021.

Presentation Information

- **Title:** Effect of Bentracimab on Platelet Inhibition and Hemostasis in Ticagrelor Patients with Uncontrolled Hemorrhage or Requiring Urgent Surgery in the REVERSE-IT Trial
- **Presenting Author:** Deepak L. Bhatt, MD, MPH, Executive Director of Interventional Cardiovascular Programs, Brigham and Women's Hospital Heart & Vascular Center and Professor of Medicine at Harvard Medical School
- **Session Title:** New Drugs and New Drug Indications in Cardiovascular Disease
- **Session Number:** LBS.07
- **Date:** November 15, 2021
- **Session Time:** 11:00 am – 12:00 pm ET
- **Presentation Time:** 11:30 am – 11:38 am ET

- **Announced Topline Results from Completed Bentracimab Phase 2b Trial**: In November 2021, PhaseBio announced topline data from its Phase 2b clinical trial of bentracimab, which was conducted in healthy, older volunteers 50-80 years old. The Phase 2b trial is a multi-center, randomized, double-blind, placebo-controlled study with 150 subjects receiving bentracimab and 50 subjects receiving placebo, all after pretreatment with dual antiplatelet therapy composed of ticagrelor and low-dose aspirin. The Phase 2b pivotal trial was conducted concurrently with REVERSE-IT, as agreed upon with the U.S. Food and Drug Administration (FDA) following an End-of-Phase 1 meeting in July 2019. The Phase 2b trial achieved its primary endpoint. The primary efficacy endpoint was reversal of ticagrelor's inhibition of platelet function in actively treated subjects versus placebo as measured using the point-of-care VerifyNow® PRUTest® platelet function assay (VerifyNow). VerifyNow is also the primary measurement used to evaluate efficacy in the ongoing REVERSE-IT Phase 3 trial. Treatment with bentracimab in the Phase 2b trial had a safety profile consistent with the Phase 1 and 2a trials previously completed by the company, with no drug-related serious adverse events or thrombotic events reported in the trial. The most common adverse events were injection site bruising and headache, with similar rates seen in both the placebo and active-treatment arms. These new data are consistent with results from PhaseBio's previously completed Phase 1 trial, conducted in healthy younger volunteers treated with ticagrelor alone and not aspirin, and Phase 2a trial, also conducted in healthy, older (ages 50-80) subjects on dual antiplatelet therapy of ticagrelor and low-dose aspirin. More than 300 subjects have been treated with bentracimab across the Phase 1, 2, and 3 clinical trials that comprise the

bentracimab development program. Additional information on the Phase 2b trial can be found on www.ClinicalTrials.gov using the identifier NCT04122170.

- **Achieved Enrollment Milestones Supporting Interim Analysis of REVERSE-IT:** In August 2021, PhaseBio announced that it had enrolled the first 143 patients in REVERSE-IT, 138 of whom required urgent surgery or an invasive procedure and five of whom experienced uncontrolled major or life-threatening bleeding. The REVERSE-IT trial is expected to enroll approximately 200 major bleeding or urgent surgery patients at sites in the United States, Canada, the European Union and China. Based on prior guidance from the FDA, to balance the two patient populations, the REVERSE-IT trial does not allow enrollment of more than approximately two-thirds of either the uncontrolled major or life-threatening bleeding population or urgent surgery or invasive procedure population. Because the total number of patients enrolled included 138 patients who required urgent surgery or an invasive procedure, the surgery cohort of the trial has been fully enrolled. With the successful completion of enrollment in this surgery cohort, REVERSE-IT trial sites have shifted focus to enrolling patients with uncontrolled major or life-threatening bleeding events. PhaseBio is seeking to accelerate enrollment of patients with uncontrolled major or life-threatening bleeding, including by working to increase the number of enrolling clinical trial sites as it believes that a broader site footprint will increase the probability of enrolling these patients. The FDA also previously indicated that an interim analysis of the first approximately 100 patients enrolled in the REVERSE-IT trial would be sufficient to support the submission of a BLA for accelerated approval of bentracimab. The FDA recommended that the 100 patients comprising the interim analysis include approximately 50 patients from each of the major or life-threatening bleeding population and urgent surgery or invasive procedure population, although the FDA noted that whether there are an adequate number of patients from either cohort would be a review issue and considered in the context of other data submitted with the BLA. PhaseBio is commencing preparation of the BLA and, subject to favorable results being observed, is targeting a BLA submission to the FDA in mid-2022.

- **Announced Approval of Bentracimab IND in China:** In August 2021, PhaseBio announced that the Investigational New Drug (IND) application for bentracimab submitted to the Center for Drug Evaluation of the China National Medical Products Administration, in collaboration with development partner, SFJ Pharmaceuticals (SFJ), has been approved. PhaseBio and SFJ anticipate enrolling the first patients at sites in China in early 2022. Patients enrolled in China will contribute to the completion of full enrollment of the REVERSE-IT trial, post interim analysis. In January 2020, PhaseBio announced a financing and co-development partnership with SFJ, and since this time, SFJ has been leading clinical development efforts in China. PhaseBio retains commercial rights to bentracimab in China and is pursuing prospective commercial partners to license the marketing rights in China and other countries in the Asia-Pacific region.

Operational Updates

- **Appointed New Member to the Board of Directors:** In September 2021, William D. Humphries, Chief Executive Officer of Isosceles Pharmaceuticals, was appointed to PhaseBio's board of directors.

- **SFJ Financing and Co-Development Agreement Update:** From execution of the co-development agreement through September 30, 2021, SFJ has funded or reimbursed $79.1 million of clinical trial costs and other expenses of the initial $90.0 million commitment under the agreement, leaving $10.9 million of funding remaining available to support the bentracimab Phase 3 program. PhaseBio is eligible to receive up to an additional $30 million of funding if specific, pre-defined clinical development milestones for bentracimab are met.

Third-Quarter Financial Results

- Cash and cash equivalents at September 30, 2021 were $56.4 million, compared to $28.1 million at December 31, 2020. The increase reflects proceeds from the March 2021 public offering of common stock and the $20.0 million upfront milestone payment received in July 2021 as part of the Alfasigma licensing agreement, partially offset by cash used in operating activities.

- Sublicense revenue for the quarter was $0.3 million and reflects recognition of a portion of the upfront milestone payment received as part of the Alfasigma licensing agreement.

- Net loss for the quarter ended September 30, 2021 was $31.9 million, compared to a net loss of $25.1 million for the same period in 2020.

- Research and development expense increased to $25.1 million for the quarter ended September 30, 2021, as compared to $17.4 million for the same period in 2020, driven by an increase in manufacturing, clinical and nonclinical development activities related to bentracimab.

- General and administrative expense increased to $3.8 million for the quarter ended September 30, 2021, compared to $3.1 million for the same period in 2020.

About PhaseBio

PhaseBio Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiovascular and cardiopulmonary diseases. PhaseBio's pipeline includes: bentracimab (PB2452), a novel reversal agent for the antiplatelet therapy ticagrelor; pemziviptadil (PB1046), a once-weekly vasoactive intestinal peptide (VIP) receptor agonist for the treatment of pulmonary arterial hypertension; and PB6440, an oral agent for the treatment of resistant hypertension. PhaseBio's proprietary elastin-like polypeptide technology platform enables the development of therapies with potential for less-frequent dosing and improved pharmacokinetics, including pemziviptadil, and drives both internal and partnership drug-development opportunities.

PhaseBio is located in Malvern, PA, and San Diego, CA. For more information, please visit www.phasebio.com, and follow us on Twitter @PhaseBio and LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "believes," "expects," "future," "intends," "potential," "projects," "target," "will," "would" and "future" or similar expressions are intended to identify forward-looking statements.

Forward-looking statements include statements concerning or implying the conduct or timing of our clinical trials and our research, development and regulatory plans for our product candidates, the timing of availability or disclosure of data from those clinical trials and the timing of planned regulatory submissions, the potential for these

product candidates to receive regulatory approval from the FDA or equivalent foreign regulatory agencies, and whether, if approved, these product candidates will be successfully distributed, marketed and commercialized, including through our partnership with SFJ. Forward-looking statements are based on management's current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements.

Risks regarding our business are described in detail in our Securities and Exchange Commission filings, including in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021. These forward-looking statements speak only as of the date hereof, and PhaseBio Pharmaceuticals, Inc. disclaims any obligation to update these statements except as may be required by law.

PhaseBio Pharmaceuticals, Inc.
Condensed Balance Sheets
(in thousands)
(unaudited)

	September 30, 2021	December 31, 2020
Assets:		
Cash and cash equivalents	$ 56,357	$ 28,122
Prepaid expenses and other current assets	8,884	12,027
Property and equipment, net	10,841	8,224
Operating lease right-of-use assets	1,586	1,927
Other non-current assets	57	57
Total assets	$ 77,725	$ 50,357
Liabilities and stockholders' deficit:		
Current portion of long-term debt	$ 5,399	$ 5,355
Current portion of deferred sublicense revenue	1,414	—
Accounts payable, accrued expenses and other current liabilities	14,644	9,605
Long-term debt, net	2,718	6,773
Operating lease liabilities, net	1,182	1,548
Deferred sublicense revenue, net	7,913	—
Development derivative liability	94,037	51,719
Other long-term liabilities	747	559
Stockholders' deficit	(50,329)	(25,202)
Total liabilities and stockholders' deficit	$ 77,725	$ 50,357

PhaseBio Pharmaceuticals, Inc.
Condensed Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Sublicense revenue	$ 335	$ —	$ 10,673	$ —
Grant revenue	—	—	—	320
Total revenue	335	—	10,673	320
Operating expenses:				
Research and development	25,066	17,416	74,752	49,721
General and administrative	3,845	3,076	11,197	9,477
Total operating expenses	28,911	20,492	85,949	59,198
Loss from operations	(28,576)	(20,492)	(75,276)	(58,878)
Other (expense) income	(3,348)	(4,651)	(11,085)	(9,312)
Net loss before income taxes	(31,924)	(25,143)	(86,361)	(68,190)
Provision for income taxes	—	—	1,600	—
Net loss	$ (31,924)	$ (25,143)	$ (87,961)	$ (68,190)
Net loss per common share, basic and diluted	$ (0.66)	$ (0.86)	$ (2.07)	$ (2.36)
Weighted average common shares outstanding, basic and diluted	48,046,307	29,243,181	42,499,685	28,941,669

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